

Appln. No. 09/869,612
Amd. dated March 17, 2004
Reply to Office Action of October 21, 2003

Amendments to the Claims

This listing of claims will replace all prior versions and listings of claims in the application:

Listing of Claims:

Claim 1 (Cancelled).

2 (Currently amended). ~~Method of preparation of A~~
method for preparing a population of circulating CD34⁺ cells
~~capable of regenerating~~ which regenerate hematopoiesis *in vivo*,
comprising:

a) administering to a donor a composition comprising growth hormone or one of its derivatives or any factor inducing growth hormone release, simultaneously or separately with a composition comprising G-CSF, in an amount sufficient to enhance the mobilization or peripheralization effect of G-CSF to further increase in said donor the number of circulating CD34⁺ cells
~~capable of regenerating~~ which regenerate hematopoiesis *in vivo* beyond that achieved by G-CSF alone; and

b) isolating a population of circulating CD34⁺ cells
~~capable of regenerating~~ which regenerate hematopoiesis *in vivo*
from the peripheral blood of said donor.

Claims 3 and 4 (Cancelled).

5 (Currently amended). ~~Method~~ The method according to claim [[4]] 2, wherein the increased number of CD34⁺ cells is more than 10, 25, 34 or 80 CD34⁺ cells per microliter of donor peripheral blood.

6 (Currently amended). ~~Method~~ The method according to claim [[4]] 2, wherein the increased number of CD34⁺ cells is at least 2×10^6 , 4×10^6 , 5×10^6 , 6×10^6 , 8×10^6 , 15×10^6 CD34⁺ cells per kilogram of donor body weight.

7 (Currently amended). ~~Method~~ The method according to ~~any one of claims 1 to 3~~ claim 2, wherein the increased number of circulating CD34⁺ cells ~~capable of regenerating~~ which regenerate hematopoiesis *in vivo* corresponds to ~~around or more than~~ about 500 or more CFU-GM per milliliter of donor peripheral blood.

8 (Currently amended). ~~Method~~ The method according to ~~any one of claims 1 to 3~~ claim 2, wherein the increased number of circulating CD34⁺ cells ~~capable of regenerating~~ which regenerate hematopoiesis *in vivo* corresponds to an increased level of CFU-C, CFU-Meg or BFU-E in donor peripheral blood.

9 (Currently amended). ~~Method~~ The method according to ~~any one of claims 1 to 3~~ claim 2, wherein the increased number of circulating CD34⁺ cells ~~capable of regenerating~~ which regenerate hematopoiesis *in vivo* substantially corresponds to a white blood

cell count of ~~around or more than~~ about 1000 or more cells per microliter of donor peripheral blood.

10 (Currently amended). ~~Method~~ The method according to ~~any one of claims 1 to 3~~ claim 2, wherein the increased number of circulating CD34⁺ cells ~~capable of regenerating~~ which regenerate hematopoiesis *in vivo* corresponds to ~~around or more than~~ about 1×10^5 or more GM-CFC per kilogram of donor or recipient body weight.

11 (Currently amended). ~~Method~~ The method according to ~~any one of claims 1 to 3~~ claim 2, wherein the circulating CD34⁺ cells ~~capable of regenerating~~ which regenerate hematopoiesis *in vivo* are CD34⁺/CD33⁺ cells and/or CD34⁺/CD38⁻ cells and/or CD34⁺/Thy-I cells and/or CD34⁺/Thy-I/CD38⁻ cells ~~and/or CD33⁺~~ cells and/or bone-marrow stem cells and/or progenitor cells and/or long-term culture initiating cells (LTC-IC) and/or cells that fulfill self renewal potential and/or cells that fulfill pluripotential characteristics and/or cells that initiate long term bone marrow culture and/or cells that can generate multiple cell lineages.

12 (Currently amended). ~~Method~~ The method according to ~~any one of claims 1 to 3~~ claim 2, wherein the target number of circulating CD34⁺ cells ~~capable of regenerating~~ which regenerate hematopoiesis *in vivo* is at least 2×10^4 LTC-IC per kg of donor or

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recipient body, ~~around or more than~~ about 2×10^6 or more CD34⁺ cells per kilogram of donor or recipient body weight, ~~around or more than~~ about 4×10^6 or more CD34⁺ cells per kilogram of donor or recipient body weight or ~~around or more than~~ about 8×10^6 or more CD34⁺ cells per kilogram of donor or recipient body weight.

13(Currently amended). ~~Method~~ The method according to ~~any one of claims 1 to 3~~ claim 2, wherein the volume of blood processed in step (b) is ~~emprised~~ in a range of about 30 to about 900 milliliters.

Claims 14-17 (Cancelled).

18(Currently amended). ~~Method~~ The method according to ~~any one of claims 1 to 3~~ claim 2, wherein growth-hormone or one of its derivatives or any factor inducing growth hormone release is administered in an amount ~~emprised~~ between 20 to 50 $\mu\text{g/kg}$ of donor body weight, in an amount ~~emprised~~ between 30 to 40 $\mu\text{g/kg}$ of donor body weight or in an amount of 33 μg per kilogram of donor body weight.

19(Currently amended). ~~Method~~ The method according to claim ~~[[17]]~~ 2, wherein the G-CSF is administered in an amount ~~emprised~~ between 3 to 15 $\mu\text{g/kg}$ of donor body weight, in an amount ~~emprised~~ between 4 to 12 $\mu\text{g/kg}$ of donor body weight or in an amount of around 5 or 10 μg per kilogram of donor body weight.

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20 (Currently amended). ~~Method~~ The method according to claim 2, wherein the administration of Growth Hormone is made three times a day and the administration of G-CSF is made daily.

21 (Currently amended). ~~Method~~ The method according to ~~any one of claims 1 to 3~~ claim 2, wherein the administration of said composition is made by parenteral, subcutaneous, intravenous, intramuscular, intraperitoneal, transdermal or buccal routes.

22 (Currently amended). ~~Method~~ The method according to ~~any one of claims 1 to 3~~ wherein the administration of said composition is daily or three times a day.

23 (Currently amended). ~~Method~~ The method according to ~~claim 1 or 2~~, wherein the administration of said composition is made over a period of 5 days or over a period of 10 days.

24 (Currently amended). ~~Method~~ The method according to ~~any one of claims 1 to 3~~ claim 2, wherein the administration begins around 7 days after the beginning of a chemotherapeutic treatment or around 2 days after the end of a chemotherapeutic treatment.

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25(Currently amended). ~~Method~~ The method according to ~~any one of claims 1 to 3~~ claim 2, wherein the growth hormone is a recombinant growth hormone.

26(Currently amended). ~~Method~~ The method according to ~~any one of claims 1 to 3~~ claim 2, wherein the growth hormone is human growth hormone.

Claims 27-55 (Cancelled).

56(New). The method according to claim 2, wherein said growth hormone or one of its derivatives or any factor inducing growth hormone release is administered at a different time than said composition comprising G-CSF.

57(New). The method according to claim 2, wherein said growth hormone or one of its derivatives or any factor inducing growth hormone release is administered simultaneously with said composition comprising G-CSF.